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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,678	12/07/2001	Glenn J. Gormley	19109DE	1340
210	7590	05/06/2005	EXAMINER	
MERCK AND CO., INC. P O BOX 2000 RAHWAY, NJ 07065-0907			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	
			DATE MAILED: 05/06/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,678

Applicant(s)

GORMLEY ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Status of Application***

1. In view of the amendment in response to the Decision on Appeal (Appeal No. 2004-0543) filed on 1/31/05, PROSECUTION IS HEREBY REOPENED.

### ***Response to Arguments***

2. Applicant's arguments filed 1/31/05 along with amendment to the claims have been fully considered but are not persuasive. Thus, the rejection issued by Board is sustained and all the claims are maintained as rejected.
3. Summary of 103 rejection (Board decision) is set forth below.

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 28-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman (US 5407944).

Claim 28 is directed to a method of treating androgenic alopecia consisting essentially of transversally administering to a person in need of such treatment a therapeutically effective amount of a 5  $\alpha$ -reductase 2 inhibitor; claim 30 specifies administration by transferal skin patch; claim 33 specifies that the 5  $\alpha$ - reductase 2 inhibitor is 17 $\beta$ -(N-tert-butylcarbamoyl)4-aza-5 $\alpha$ -androst-1-ene-3-one), otherwise known as "Finasteride" ;claim 36 is directed to a skin patch consisting essentially of a 5  $\alpha$ -reductase 2 inhibitor.

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Goldman(US'944, hereinafter) teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and 5  $\alpha$ -reductase inhibitor(column 2, lines 42-46; column 6, lines 5-9), "A highly preferred inhibitor of ....5  $\alpha$ -reductase for use in [Goldman's] compositions and methods" (column 5, lines 43-44), indeed the only 5- $\alpha$ -reductase inhibitor specifically mentioned, is finasteride(column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner"(column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transderma patches or preparation"(column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5  $\alpha$ -reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preferred" 5  $\alpha$ -reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic by transdermal administration of a pharmaceutical preparation, e.g. a transdermal skin patch, consisting essentially of a 5  $\alpha$ -reductase inhibitor, e.g. finasteride, in view of Goldman's explicit suggestions.

"Consisting Essentially Of"

Applicants amend the claims and argues that the pending claims 218-37 are patentably distinguish over Goldman in view of the transition phrase "consisting essentially of"(Request for reconsideration and withdrawal of the rejection, see Remark

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section at page 6, filed 1/31/05 ). According to applicants, the recitation of an active component in those claims "consisting essentially of" 5  $\alpha$ -reductase inhibitor (claims 28-32 or finasteride (claim 33-37) exclude a vasodilator or an estradiol disclosed by Goldman.

The examiner disagree.

As stated in PPG Indus., Inc. V. Guardian Indus. Corp., 156 F 3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354(Fed. Cir. 1998),

By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format.(Emphasis added).

Here, applicants' argument that "consisting essentially of" excludes those vasodilator or estradiols of Goldman is an example of ipse dixit reasoning. Applicants do not describe the "basic and novel properties of the invention," or explain why or establish how the vasodilators or estradiols of Goldman materially affects those properties.

Additionally, it is apparent from applicant's specification(pages 7-9) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the vasodilators or estradiols of Goldman would "materially affect" the basic and novel properties of the invention and, accordingly, be excluded by the phrase "consisting essentially of," whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase "consisting essentially of." Applicants have not made it clear, in their specification or in their request for reconsideration, what they

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"regarded as constituting a material change in the c the basic and novel properties of the invention."

**Conclusion**

1. No claim is allowed.
2. Board decision(103 rejection) is sustained. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.
3. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page is reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM  
PRIMARY EXAMINER**

Vickie Kim  
Primary Patent Examiner  
May 3, 2005  
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